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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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HM22/1002

EXAMINER	
DRAPER, G	
ART UNIT	PAPER NUMBER
1647	7

DATE MAILED: 12-02-00

For Restriction and Sequence Compliance

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1 - 20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☑ Claims 1 - 20 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

1. **Part III: Detailed Office Action for Restriction and/or Sequence Compliance**

2. ***Restriction Requirement:***

This application was filed under 35 USC 371, therefore the restriction will be set forth accordingly.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 7-10, drawn to DNA encoding a beacon protein and composition of the protein, classified in classes 536, 435, 530, subclasses 23.5, 69.1+, 350+.

II. Claims 11-13 and possibly claim 16, drawn to methods of treatment using the protein, classified in class 514, subclass 2+. [Note, claim 16 is a non-statutory "use" claim, as well as an improperly multiply-dependent claim, which requires correction of both of these matter. However, this claim is being grouped with the other claims based on a reasonable interpretation of what is meant and/or intended. Depending on the correction of such by amendment, this claim may be further restricted.]

III. Claims 14-15, drawn to antibodies to the protein, classified in class 530, subclass 388.24+.

IV. Claims 17 and possibly 19, drawn to methods of detecting the protein using the antibody, classified in class 435, subclass 7.1.

V. Claims 18 and possibly 19, drawn to methods of detecting expression of the protein or levels of mRNA, classified in class 435, subclass 6+.

The inventions are distinct, each from the other because:

Each of these Groups do not represent a common and special technical feature that would unite such for the examination of each and one invention (See Chapter 1800). Group I is directed to products encompassing the DNA and encoded protein and compositions of such; whereas Group III is directed to antibodies, and Groups II, IV and V are directed to distinct methods which do not represent a common and single special technical feature that is required one for the other, no does each of these methods require each of the other products of the other Group(s). Likewise, both of the products of Group I is not required for the products of Group III, nor is each of these products required for each of the methods so as to form a single technical feature. Clearly, there is no common or unifying technical feature which requires the examination of each of Groups I---V..

It is also noted that even according to U. S. Restriction practice the following rationale is offered to support restriction and/ or a lack of unity for a single common and unifying technical feature for each of the claims. Thus, the inventions are further distinct, each from the other because, although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different products, restriction and/or a holding of lack of unity is deemed to be proper because the products of the different groups appear to constitute structurally, physically, functionally and patentably distinct inventions. Furthermore, the products of Groups I and III are not required one for the other; nor is each of the products used in or required for each of the methods.

In a similar manner it is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different methods, restriction and/or a holding of lack of unity is deemed to be proper because the methods appear to constitute patentably distinct inventions. The inventive methods of Groups II, IV and Groups V require the use of different steps/methods; elements/agents that are physically and functionally distinct; there are different starting elements and the final outcome/results are different for these different methods that cover various diagnostics and therapeutic methods; and if determined to be

patentable they would also be patentably distinct. Furthermore, these methods are not required one for the other, nor does each of the methods require the use of each of the products of Groups I and III.

Because these inventions are distinct for the reasons given above; they do not represent a single unifying special technical feature, and the inventions have acquired a separate status in the art as shown by their different classifications which are not co-extensive. And there are different issues for the search and examination of each group, which would be unduly burdensome, accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

3. Sequence Compliance:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend

the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

The file appears to have a paper copy, but no disk or other forms of compliance has been met. See the attachment.

4. Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1647, whose telephone number is (703) 308-4232.** Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800